DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 30 1997

Re: ALLEGRA™
Docket No. 96E-0386

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,254,129, filed by Hoechst Marion Roussel, Inc., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for ALLEGRA™, the human drug product claimed by the patent.

The total length of the regulatory review period for ALLEGRA™ is 996 days. Of this time, 635 days occurred during the testing phase and 361 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: November 4, 1993.

   FDA has verified the applicant's claim that the date the Investigational New Drug application became effective was on November 4, 1993.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: July 31, 1995.

   FDA has verified the applicant's claim that the New Drug Application (NDA) for ALLEGRA™ (NDA 20-625) was initially submitted on July 31, 1995.

3. The date the application was approved: July 25, 1996.

   FDA has verified the applicant's claim that NDA 20-625 was approved on July 25, 1996.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

for Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Louis J. Wille
Hoechst Marion Roussel, Inc.
2110 East Galbraith Rd.
P.O. Box 156300
Cincinnati, OH 45215-6300